



A Manager's Guide to the Design and Conduct of Clinical Trials

Phillip I. Good

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This newly updated edition of the benchmark guide to computer-assisted clinical trials provides a comprehensive primer for prospective managers. It covers every critical issue of the design and conduct of clinical trials, including study design, organization, regulatory agency liaison, data collection and analysis, as well as recruitment, software, monitoring, and reporting.

Keeping the same user-friendly format as the original, this Second Edition features new examples and the latest developments in regulatory guidelines, such as e-submission procedures and computerized direct data acquisition. The new edition also reflects the increasing globalization of clinical trial activities, and includes new information about international standards and procedures, including the Common Technical Document and CDISC standards.

This step-by-step guide is supported by handy checklists and extracts from submitted protocols. Experienced author and consultant Phillip Good incorporates humorous yet instructive anecdotes to illustrate common pitfalls. Based on the proven industrial formula of planning, implementing, and finally performing essential checks, the book's three sections-"Plan," "Do," and "Check"-include the following material:

- * Should the trials be conducted?
- * Put it in the computer and keep it there
- * Staffing for success
- * Designing trials and determining sample size
- * Budgeting
- * Recruiting and retaining patients and physicians
- * Data management
- * Monitoring the trials
- * Data analysis
- * After action review
- * Exception handling

Executive and managerial professionals involved in the design and analysis of clinical experiments, along with clinical research associates, biostatisticians, and students in public health will find *A Manager's Guide* an indispensable resource.

Praise for the First Edition:


". . . readable, informative and at times witty . . . never stops being concise and well written . . . a book worth a read . . ."

-Statistics in Medicine

"The book is very prescriptive and full of lists and tables with which to guide managers in making effective decisions in using computer-assisted clinical trials in pharmaceutical studies." -Technometrics

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